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(54) Surgical aid endowed with osteotropic activity.

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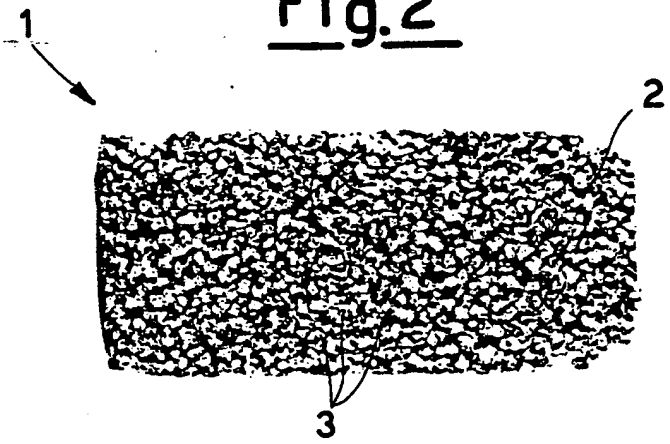
Fig.2



EP 0 329 239 A2

SURGICAL AID ENDOWED WITH OSTEOTROPIC ACTIVITY

The present invention is concerned with a surgical aid performing an osteotropic action.

During the operations of orthopedic surgery, odontiatric surgery, and in parodontium pathology, the need usually occurs for:

- filling hollows,
- removing defects and differences in level of bony planes,
- reconstructing portions of bony tissue, by operating in such a way as to favour a rapid restoration of the morphology of the bony segment the tissue of which suffered lesions or underwent modifications.

In order to meet the above needs, the use of various types of hydroxy-apatite in presently known.

From an operative viewpoint, the granules of hydroxy-apatite are manually deposited on the region to be treated, so that they may behave as an osteotropic element. Therefore, after healing, the hydroxy-apatite granules are incorporated in an at all compatile way inside the bony tissue formed.

However, the operation of deposition of the granules of hydroxy-apatite calls for a great skill by the surgeon.

Such a great skill is essential for the surgeon, in order that he can correctly meter the necessary amount of hydroxy-apatite, and to house it in the nearby of the lesion in such a way that, after the wound being sutured, the granules of said hydroxy-apatite get not dispersed during the surgical healing process.

If hydroxy-apatite is not correctly metered, but, for example, a lower than optimum amount thereof is metered, after the healing a satisfactory clinic result is not obtained. If, for example, hydroxy-apatite is metered in a larger amount than as necessary, the healing process ends anyway with a poor clinic result; moreover, the probability is higher, that the granules get dispersed in correspondence of the bony lesion, therefore moreover causing a waste of a particularly expensive material.

Said considerable skill is furthermore required from the surgeon, in order that he may correctly insert the granules of hydroxy-apatite inside hollows which are difficult to reach, extemporarily creating, by resorting to makeshift means, small instruments or guides, which are capable of fulfilling the surgical requirements.

Particularly difficult situations have to be frequently confronted with in case of odontiatric operations, during which the bony tissue has to be integrated in particularly narrow areas.

The purpose of the present invention is of providing a surgical aid performing an osteotropic action, which is capable of obviating the above-said drawbacks.

Such purposes are achieved by a surgical aid endowed with an osteotropic activity, characterized in that it comprises a base and a suspended substance, which constitutes the active element, with said base being constituted by gelatine of pharmacologic grade, in a pure state, and the suspended matter being constituted by ceramic hydroxy-apatite dispersed in the base.

The advantages attained by means of the present invention essentially consist in that:

- it can be easily used, in that the metering of the granules of hydroxy-apatite is not required;
- it makes it possible the only necessary amount to be used, with the operation costs being reduced;
- it can be easily and stably applied (in that it has a firm structure, not a simply granular structure), without resorting to special equipment pieces being necessary;
- it is easily anchored in the area in which it is necessary, with no risks that it may get dispersed or displaced during the clinic healing process;
- it is ductile and malleable, with the possibility of use of the product being hence increased.

The invention is illustrated for merely exemplifying, and non-limitative, purposes, in the figures of the hereto attached drawing tables.

Figure 1 shows a surgical aid according to the present invention, in a form which makes it possible it to be immediately used, in that said surgical aid is given the shape of a laminar structure, with a high density of granules of active material;

Figure 2 shows a surgical aid according to the present invention, also in a form which makes it possible it to be immediately used, in that said surgical aid is given the shape of a laminar structure with a low density of granules of active material.

Referring to the above cited figures, the surgical aid according to the present invention, generally indicated by the reference numeral 1, comprises a base and a suspended substance, which constitutes the active element. The base 2 is constituted by gelatine of pharmacologic grade, in a pure state (hereinunder simply referred to as the "gel"), and the suspended matter is constituted by granules 3 of ceramic hydroxy-

apatite dispersed throughout the base by kneading.

In order to give the product a certain plasticity, glycerol is added.

The optimum chemical composition of the surgical aid in hydrate phase is indicatively as follows:

- hydroxy-apatite	61.35%
- gel	13.56%
- glycerol	12.65%
- water	12.44%

The so-obtained product is dried by evaporation under vacuum, with it being heated to a temperature not higher than 40 °C, in order to prevent the gel from undergoing any modifications.

The end product obtained after water evaporation, and therefore of the anhydrous phase, is as follows:

- hydroxy-apatite	70.00%
- gel	15.05%
- glycerol	14.04%
- water	0.91%

The so-obtained product, which is malleable and ductile, is mechanically shaped so as to give it the shape of very thin sheets, small rods, filaments, or any other shapes which make it possible it to be easily and promptly used after being sterilized by means of gamma rays.

The hydroxy-apatite used in order to form the surgical aid is in the form of granules having a diameter indicatively comprised within the range of from 0.5 to 1.8 mm.

The characteristics of elasticity and flexibility are mainly influenced by the presence of glycerol; more precisely, with increasing glycerol percentage, the characteristics of flexibility and elasticity increase; with the percentages of glycerol gradually decreasing, a substantially more and more rigid product is obtained.

Therefore, a change in glycerol percentage relatively to the gel percentage is provided, which is comprised within the range of about ±4%.

The osteotropic aid shown in Figure 1 is of the laminar type, with a high granular density, whilst the aid shown in Figure 2 is of the type with a low granular density.

The application of the aid shown in Figure 1 is particularly indicated for the reconstruction of bone defects in some parodontium illnesses and the like; whilst the aid shown in Figure 2 is used after various resections of benign tumors, after the removal of bony tissue owing to traumatic causes, in the substitution of special endoprostheses, and the like. The granules 3 of hydroxy-apatite retained by the base 2 of interstitial gel are visible.

For the application, the surgical aid in anhydrous phase is used cut into pieces of the required size by means of a common pair of scissors, or suitably dimensioned pre-formed pieces are used.

The gel prevents the granules of hydroxy-apatite 3 from getting dispersed both during the operation, and during the clinic healing process.

Therefore, the granules of hydroxy-apatite are progressively encapsulated inside the bony tissue during the step of cicatricial rebuilding.

The hydrate gel is progressively dissolved and metabolized.

Claims

1. Surgical aid endowed with an osteotropic activity, characterized in that it comprises a base and a suspended substance, which constitutes the active element, with said base being constituted by gelatine of pharmacologic grade, in a pure state, and the suspended matter being constituted by ceramic hydroxy-apatite dispersed in the base.

2. Aid according to claim 1, characterized in that said aid contains glycerol.

3. Aid according to claim 2, characterized in that two phases thereof are provided: an anhydrous phase and a hydrate phase, with said anhydrous phase substantially comprising:

- hydroxy-apatite	70.00%
- gel	15.05%
- glycerol	14.04%
- water	0.91%

and said hydrate phase substantially comprising:

- hydroxy-apatite	61.35%
- gel	13.56%
- glycerol	12.65%
- water	12.44%

4. Aid according to claim 3, characterized in that the percentage of glycerol is variable relatively to the gel percentage, by a value of ±4%.

5. Aid according to claim 3, characterized in that hydroxy-apatite is as granules, the diameter of which is comprised within the range of from 0.5 to 1.8 mm.

6. Aid according to claim 3, characterized in that in the anhydrous state it is both elastic and flexible.

7. Process for the production of a surgical aid, characterized in that it comprises
- a first step during which the ingredients are mixed, with a hydrate phase being obtained eventually, the percentages of which are identical to those as stated in claim 3,
- a second step during which a drying is carried out, in order to obtain an anhydrous phase,
- a third sted during which the product is given the shape of thin sheets and/or filaments,
- a fourth step of sterilization and packaging.

8. Process according to claim 6, characterized in that the drying step is carried out at a temperature lower than 40° C, and under vacuum conditions.

9. Process according to claim 6, characterized in that the sterilization is carried out by irradiation with gamma rays.

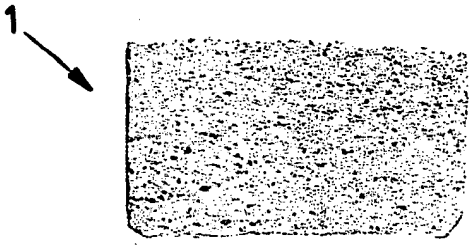
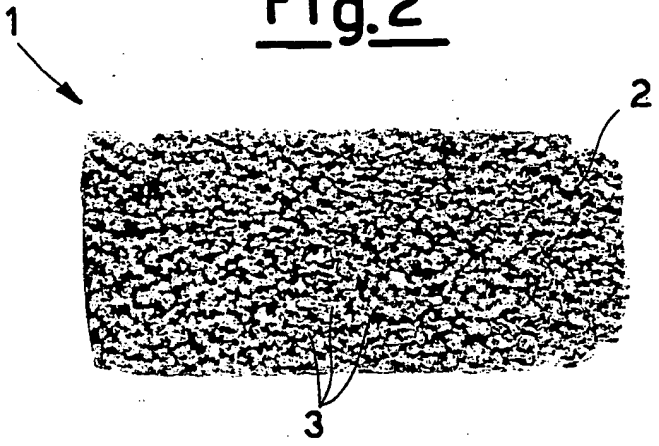


Fig.1

Fig.2



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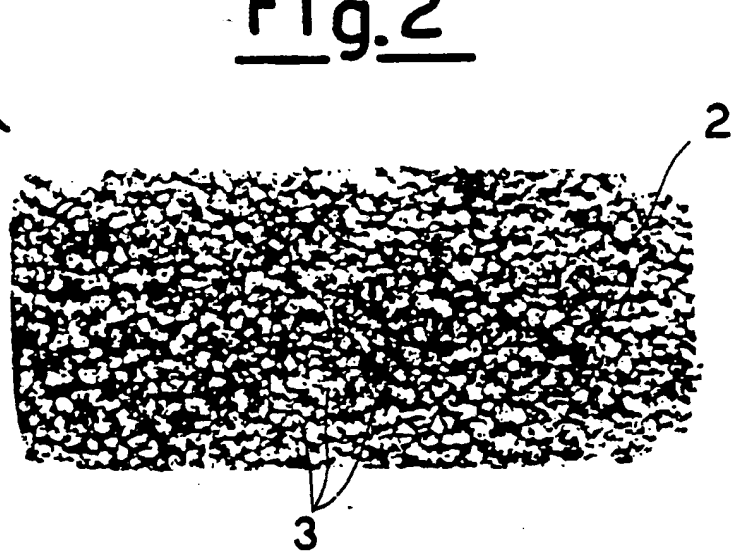

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EUROPEAN SEARCH REPORT

Application Number

EP 89 20 0330

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
X	WO-A-8 601 113 (G. BRINKS) * Claims 1-2; page 2, line 26 - page 3, line 7; page 3, lines 21-35; pae 4, lines 19-22 *	1,3,5	A 61 L 27/00 A 61 L 25/00 A 61 K 6/00
X	US-A-4 349 470 (O. BATTISTA) * Example 5 *	1,5	
Y	US-A-4 357 935 (W. FRANTZICH) * Column 1, lines 29-36 *	9	
Y,P	EP-A-0 270 254 (COLLAGEN CORP.) * Claims *	9	
A	EP-A-0 147 021 (ED. GEISTLICH SOEHNE)		

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

A 61 L
A 61 K

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	17-05-1990	COUSINS-VAN STEEN G.I.L.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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